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July 8, 2013

**VIA E-MAIL:** [dsmall@foleyandsmall.com](mailto:dsmall@foleyandsmall.com)

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1002 E. Jefferson Blvd.  
South Bend, IN 46617

Re: New England Compounding Pharmacy, Inc. Products Liability Litigation  
United States District Court; Fourth District of Massachusetts  
MDL No. 1:13-MD-02419  
Subpoena Served on The South Bend Clinic

Dear Doug:

Please accept this letter as The South Bend Clinic's Fed. R. Civ. P. 45(c)(2)(b) objections to your clients' subpoena for production of documents and subpoena for a deposition. We tried to contact you to discuss ways to resolve the objections, but learned that you are on vacation. To meet the Court's schedule so objections can be heard at the July 18, 2013 status conference, we will have to file our objections by July 10, 2013. These written objections will explain our position and should provide the framework to help us resolve the issues after you return from vacation, and before the July 18, 2013 status conference.

A. Deposition Subpoena

The South Bend Clinic objects to the subpoena to take a deposition of its representative. Your June 25, 2013 e-mail to Laura Seng of our office and Lyle Hardiman of Hunt Suedhoff Kalamaros states that an automatic stay was issued in NECC's Chapter 11 bankruptcy case. That stay applies broadly to any action involving NECC and its corporate-related entities. Since NECC is the principal defendant in the MDL actions, it has the right to appear and ask questions at any deposition. The proposed deposition would affect these parties' rights and therefore potentially violate the automatic stay. Further, the MDL orders that you sent appear to address production of documents, not depositions.

The subpoena for a deposition also violates Fed. R. Civ. P. 45(b)(1). The Rule states, "If the subpoena requires that person's attendance, tendering the fees for one day's attendance and the mileage allowed by law." No fee was tendered, so the subpoena is invalid.

If the bankruptcy stay is lifted (or an accommodation reached with NECC's bankruptcy trustee) and the required fee is provided, we will need to change the date of the deposition. The

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person who would likely be designated for many of the topics has vacation in July. It would make sense to set the deposition issue aside for now, without either party waiving any rights. Then, as the issues on the document production are resolved and the documents are produced, you can determine whether a deposition is even needed, and on what specific topics. Please let us know if you agree with that proposal.

**B. Subpoena for Production of Documents**

The subpoena for production of documents refers to an "Exhibit B." However, the subpoena only contains an "Exhibit A." Therefore, it is ambiguous. We assume that the categories of documents that you request are those identified by Paragraphs 1-21 of Exhibit A. If so, each of those is copied below, followed by the South Bend Clinic's objection and our proposed resolution. This should help us resolve issues after you return to the office, and before the July 18, 2013 hearing.

1. Any and all documents and/or electronically stored information ("ESI") reflecting, and/or related in any way whatsoever to, the procurement of methylprednisolone acetate ("MPA") and any other injectable steroid preparations from New England Compounding Pharmacy, Inc. ("NECP") during the two-year period immediately preceding October 6, 2012, including without limitation of the foregoing, information reflecting dates of shipment and/or receipt, quantities of shipment, lot numbers and other identifying labels, sizes of containers of steroid preparation, the cost you paid for the steroid preparation, applicable warranties, shelf life, expiration dates, requirements and instructions for shipment and/or storage, and the specific identity of the preparation being purchased. Also including account information, prescriptions submitted to NECP, prescription order forms, NECP charges for MPA (before and after any discounts applied).

**OBJECTION:** The Request is overbroad because it is not limited to methylprednisolone acetate, the drug that is the subject of the lawsuits at issue. It is also not limited to a relevant time period, and exceeds the January 2011 – November 2012 period contained in ¶2 of the Court's June 21, 2013 order [Dckt. 192]. The request for costs paid and NECP charges is not reasonably calculated to lead to the discovery of admissible evidence. Further, the request for "prescriptions submitted to NECP, prescription order forms" would disclose confidential patient information of people who are not parties to the lawsuits underlying the MDL. Moreover, the Request seeks information that is privileged and protected from disclosure by the peer review committee privilege under Indiana Code 34-30-15-9, or the professional review activity privilege of the Health Care Quality Improvement Act 42 USC § 11137(b).

**Proposed Resolution:** The South Bend Clinic proposes to produce documents related to the procurement of methylprednisolone acetate from NECP from January 2011 through November 2012, which identify dates of shipment, receipt of shipment, quantities of shipment, lot numbers and other identifying information, and any documents that were shipped with the MPA as retained in the normal course of business.

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2. Any and all documents and/or ESI reflecting, and/or related in any way whatsoever to, the procurement of MPA, or its generic or name-brand equivalent, from any producer, compounding facility or manufacturer other than NECP, since October 6, 2007, including without limitation of the foregoing, information reflecting dates of shipment and/or receipt, quantities of shipment, lot numbers and other identifying labels, sizes of containers of the product, the cost you paid for the product, applicable warranties, shelf life, expiration dates, requirements and instructions for shipment and/or storage, and the specific identity of the preparation being purchased.

**OBJECTION:** The Request is overbroad and not reasonably calculated to lead to the discovery of admissible evidence because it is not limited to the January 2011 – November 2012 time period established in the Court's June 21, 2013 order [Dckt. 192, ¶2], and is not limited to MPA procured from Defendant New England Compounding Pharmacy, Inc. Information regarding the costs paid for the MPA is also not reasonably calculated to lead to the discovery of admissible evidence.

**Proposed Resolution:** The South Bend Clinic does not understand why MPA procured by a non-party from another non-party compounding facility is relevant to your clients' lawsuits against NECP. Please withdraw Request No. 2.

3. Any and all documents and/or ESI reflecting, and/or related in any way whatsoever to, the procurement of cardioplegic solution from NECP during the two-year period immediately preceding October 6, 2012, including without limitation of the foregoing, information reflecting dates of shipment and/or receipt, quantities of shipment, lot numbers and other identifying labels, sizes of containers of cardioplegic solution, the cost you paid for the cardioplegic solution, applicable warranties, shelf life, expiration dates, and requirements and instructions for shipment and/or storage. Also including prescriptions submitted to NECP, prescription order forms, NECP charges for cardioplegic solution (before and after any discounts applied).

**OBJECTION:** The Request is overbroad because it is not limited to a relevant time period, and exceeds the January 2011 – November 2012 period contained in ¶2 of the Court's June 21, 2013 order [Dckt. 192].

**Proposed Resolution:** The South Bend Clinic did not cardioplegic solution from NECP, so no responsive documents and/or ESI exist.

4. Any and all documents and/or ESI reflecting, and/or related in any way whatsoever to, the procurement of ophthalmic solution from NECP during the two-year period immediately preceding October 6, 2012, including without limitation of the foregoing, information reflecting dates of shipment and/or receipt, quantities of shipment, lot numbers and

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other identifying labels, sizes of containers of ophthalmic solution, the cost you paid for the ophthalmic solution, applicable warranties, shelf life, expiration dates, and requirements and instructions for shipment and/or storage. Also including prescriptions submitted to NECP, prescription order forms, NECP charges for ophthalmic solution (before and after any discounts applied).

**OBJECTION:** The Request is overbroad because it is not limited to a relevant time period, and exceeds the January 2011 – November 2012 period contained in ¶2 of the Court’s June 21, 2013 order [Dckt. 192]. The request for costs paid and NECP charges is not reasonably calculated to lead to the discovery of admissible evidence. Further, the request for “prescriptions submitted to NECP, prescription order forms” would disclose confidential patient information of people who are not parties to the lawsuits underlying the ophthalmic solution. Moreover, the Request seeks information that is privileged and protected from disclosure by the peer review committee privilege under Indiana Code 34-30-15-9, or the professional review activity privilege of the Health Care Quality Improvement Act 42 USC § 11137(b).

**Proposed Resolution:** The South Bend Clinic proposes to produce documents related to the procurement of ophthalmic solution from NECP from January 2011 through November 2012, which identify dates of shipment, receipt of shipment, quantities of shipment, lot numbers and other identifying labels, and any documents that were shipped with the ophthalmic solution.

5. Any and all documents and/or ESI reflecting, and/or related in any way whatsoever to, the procurement of preservative-free saline solution from NECP during the two-year period immediately preceding October 6, 2012, including without limitation of the foregoing, information reflecting dates of shipment and/or receipt, quantities of shipment, lot numbers and other identifying labels, sizes of containers of saline solution, the cost you paid for the saline solution, applicable warranties, shelf life, expiration dates, and requirement and instructions for shipment and/or storage. Also including prescriptions submitted to NECP, prescription order forms, NECP charges for preservative-free saline solution (before and after any discounts applied).

**OBJECTION:** The Request is overbroad because it is not limited to a relevant time period, and exceeds the January 2011 – November 2012 period contained in ¶2 of the Court’s June 21, 2013 order [Dckt. 192]. The request for costs paid and NECP charges is not reasonably calculated to lead to the discovery of admissible evidence. Further, the request for “prescriptions submitted to NECP, prescription order forms” would disclose confidential patient information of people who are not parties to the lawsuits underlying MDL.

**Proposed Resolution:** The South Bend Clinic did not purchase preservative-free saline solution from NECP, so no responsive documents and/or ESI exist.



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6. Any and all documents and/or ESI reflecting, and/or related to, the identification of each and every patient that was administered an NECP product during the two-year period immediately preceding October 6, 2012, including patient name, address, date of birth, identification of product administered, and date product was administered.

**OBJECTION:** The Request is overbroad because it is not limited in scope to patients who are your clients in the MDL or any other legal proceeding. The Request also seeks confidential medical information/protected health information regarding patients who are not your clients. The Request is also not limited to the January 2011 through November 2012 time period allowed by the Court's June 21, 2013 order [Dckt. 192]. The Request is not limited to the drugs at issue in the lawsuits that are a part of the MDL. The Request does not direct The South Bend Clinic to produce the protected health information to the "Vendor" as described in the Court's June 21, 2013 order [Dckt. 192]. The Request is also unduly burdensome because The South Bend Clinic has already produced all medical records related to four of your Indiana clients, so the production would be duplicative.

**Proposed Resolution:** The South Bend Clinic will produce the medical records for any person that provides a proper medical record release in accordance with Indiana Code 16-39-1-4 and the Health Insurance Portability and Accountability Act of 1996 (42 USC § 1320d et. seq.) and the regulations promulgated thereunder (collectively "HIPAA"). It is my understanding that you have already provided releases for four of your clients, and their medical records were produced.

7. Any and all documents and/or ESI reflecting or containing communications (written or otherwise) between The South Bend Clinic ("Healthcare Provider"), its employees, principals, partners, and/or agents, and NECP, its employees and/or agents, during the two-year period immediately preceding October 6, 2012, including, but not limited to, any complaints or adverse event reports made to NECP by the Healthcare Provider.

**OBJECTION:** The Request is overbroad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence because it is not limited to communications regarding issues raised in the lawsuits that are part of the MDL. The Request also seeks documents that may include confidential medical information/protected health information of its patients.

**Proposed Resolution:** The South Bend Clinic will produce written communications between it and NECP from October 6, 2010 to October 6, 2012, with the identities of patients who have not provided releases for medical records redacted.

8. Any and all documents and/or ESI reflecting or containing information obtained by the Healthcare Provider, its employees and/or agents, regarding NECP, including without limitation of the foregoing, NECP's qualifications, certifications or accreditations, or lack

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thereof, regulatory compliance, lack of regulatory compliance, operations, enforcement actions, suitability for conducting its business, legal actions and/or warnings, brochures, policies and procedures, ordering and delivery information company overviews, standard operating procedures, executive summaries, attachments A, B or others (relating to HIPAA, NECP policies and procedures, or other information).

**OBJECTION:** The Request is vague and ambiguous in its references to "suitability for conducting its business," "ordering and delivery information company overviews," and "attachments A, B or others (relating to HIPAA, NECP policies and procedures, or other information)." There were no attachments to the exhibit to the subpoena.

**Proposed Resolution:** The South Bend Clinic will produce information it acquired prior to October 6, 2012 regarding NECP.

9. Any and all documents and/or ESI reflecting or containing information obtained by, or communications received by, the Healthcare Provider, its employees and/or agents, concerning the fitness of any products purchased or obtained from NECP for their intended use, during the two-year period immediately preceding October 6, 2012, including but not limited to any environmental testing results, microbiology reports or certificates of analysis.

**OBJECTION:** The Request is overbroad and not reasonably calculated to lead to the discovery of admissible evidence because it is not limited to the drugs that are the subject of the suits underlying the MDL, and exceeds the January 2011 through November 2012 time period contained in the Court's June 21, 2013 order [Dckt. 192].

**Proposed Resolution:** The South Bend Clinic will produce responsive documents regarding methylprednisolone acetate and ophthalmic solution, obtained from NECP from January 2011 through November 2012, sent to or obtained by The South Bend Clinic, from the CDC, the FDA or the Indiana Department of Health. The South Bend Clinic did not purchase cardioplegic solution or preservative-free saline solution from NECP, so responsive documents do not exist.

10. Any and all documents and/or ESI reflecting or containing information obtained by, or sent to, the Healthcare Provider, its employees and/or agents, from the Centers for Disease Control and Prevention, the Federal Food and Drug Administration, and/or any other Federal, state or local regulatory agency, concerning the fitness of any products manufactured, compounded or produced by NECP for their intended purpose.

**OBJECTION:** The Request is overbroad and not reasonably calculated to lead to the discovery of admissible evidence because it is not limited to the drugs underlying the individual claims that constitute the MDL suit. Further, the Request is unduly burdensome as information and documents publically posed on the websites of the Centers for Disease Control and

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Prevention and the Food and Drug Administration as “open letters” and instructions to all healthcare providers who purchased medications from NECP are obtainable from the original source agencies.

**Proposed Resolution:** The South Bend Clinic will produce responsive documents regarding methylprednisolone acetate and ophthalmic solution, obtained from NECP from January 2011 through November 2012. The South Bend Clinic will produce any responsive documents sent to The South Bend Clinic by such agencies, but will not research and produce publically posted documents of the various state and federal agencies named in the Request.

11. Any and all documents and/or ESI reflecting or containing communications between the Healthcare Provider and any federal or state agency (including, but not limited to state licensing authorities, the Food and Drug Administration, and the Centers for Disease Control and Prevention) in connection with the procurement of products from any compounding pharmacy.

**OBJECTION:** The Request is overbroad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence because it is not limited in scope to procurements from NECP of methylprednisolone acetate, cardioplegic solution, ophthalmic solution, and preservative-free saline solution, or to the relevant agencies.

**Proposed Resolution:** The South Bend Clinic will produce communications with the CDC, FDA and Indiana Department of Health regarding methylprednisolone acetate and ophthalmic solution obtained from NECP from January 2011 through November 2012. The South Bend Clinic did not purchase cardioplegic solution and preservative-free saline solution from NECP, so no responsive documents exist.

12. Any and all documents and/or ESI reflecting or containing marketing information from NECP, NECP’s agents, or any sales company or person marketing, selling, or attempting to sell products on behalf of NECP.

**OBJECTION:** The Request is overbroad and not reasonably calculated to lead to the discovery of admissible evidence because it is not limited to the drugs underlying the individual claims that constitute the MDL suit.

**Proposed Resolution:** The South Bend Clinic will produce responsive documents regarding methylprednisolone acetate and ophthalmic solution obtained from NECP from January 2011 through November 2012.

13. Any and all documents and/or ESI reflecting or containing agreements, contracts and/or warranties between the Healthcare Provider and NECP, NECP’s agents, or any sales

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company or person marketing, selling, or attempting to sell products on behalf of NECP.

**OBJECTION:** The Request is overbroad and not reasonably calculated to lead to the discovery of admissible evidence because it is not limited to the drugs underlying the individual claims that constitute the MDL suit.

**Proposed Resolution:** The South Bend Clinic will produce responsive documents regarding methylprednisolone acetate and ophthalmic solution obtained from NECP from January 2011 through November 2012.

14. Any and all documents and/or ESI reflecting or containing recall notices received by the Healthcare Provider pertaining to products produced by NECP, including without limitation of the foregoing, the date, time and manner of receipt of the recall notices, the specific person or persons within the Healthcare Provider who received the notice, and the substance of the notice.

**Response:** The South Bend Clinic will produce responsive documents.

15. Any and all documents and/or ESI reflecting or containing communications made or issued by the Healthcare Provider, its employees and/or agents, in response to any recall notice regarding NECP products, including without limitation of the foregoing, the date, time and manner of transmission of the communication, the person(s) to which the communication was directed, and the person at the Healthcare Provider who made or delivered the communication.

**OBJECTION:** A response to the request would disclose confidential patient information of people who are not parties to the lawsuits that comprise the MDL, and are not clients of the requesting attorney.

**Proposed Resolution:** The South Bend Clinic will produce all responsive communications, with the information that identifies patients who have not provided redacted medical releases. To the extent that form letters were utilized to communicate information to patients, sample letters will be produced in lieu of individualized redacted letters. The South Bend Clinic will not produce medical records of individual patients reflecting specific physician-patient information interactions related to care and treatment of the individual patient in response to Request No. 15.

16. Any and all documents regarding any investigation or inquiry the Healthcare Provider performed related to attempts by NECP to comply with United States Pharmacopeia – National Formulary, Chapter 797 (USP – NF General Chapter 797, entitled “Pharmaceutical Compounding – Sterile Preparations”).



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**Response:** The South Bend Clinic will produce responsive documents.

17. Any and all policies of insurance, including without limitation of the foregoing, professional liability, malpractice, products liability, general liability, and comprehensive or umbrella policies, issued to the Healthcare Provider and/or its principal officers and directors and/or any physician working for or on behalf of the Healthcare Provider, for the policy periods including calendar years 2011, 2012 and 2013.

**OBJECTION:** The Request is overbroad and not reasonably calculated to lead to the discovery of admissible evidence. The South Bend Clinic is not a Defendant in any of the lawsuits that comprise the MDL, so its insurance policies are not discoverable.

**Proposed Resolution:** The South Bend Clinic requests that you withdraw Request No. 17.

18. Articles of Incorporation and/or By-Laws applicable to the Healthcare Provider for calendar years 2011, 2012 and 2013.

**OBJECTION:** The Request is overbroad and not reasonably calculated to lead to the discovery of admissible evidence. The South Bend Clinic is not a Defendant in any of the lawsuits that comprise the MDL, so its Articles of Incorporation and By-Laws are not discoverable.

**Proposed Resolution:** The South Bend Clinic requests that you withdraw Request No. 18.

19. Any and all documents and/or ESI reflecting or containing the names, addresses and positions (President, Vice-President, Director, etc.) within the Healthcare Provider of all officers and directors of the Healthcare Provider during the calendar years 2011, 2012 and 2013.

**OBJECTION:** The Request is overbroad and not reasonably calculated to lead to the discovery of admissible evidence. The South Bend Clinic is not a Defendant in any of the lawsuits that comprise the MDL, so the identities of its officers and directors are not discoverable.

**Proposed Resolution:** The South Bend Clinic requests that you withdraw Request No. 19.

20. Any and all documents showing the entities or individuals with an ownership interest in the Healthcare Provider.

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**OBJECTION:** The Request is overbroad and not reasonably calculated to lead to the discovery of admissible evidence. The South Bend Clinic is not a Defendant in any of the lawsuits that comprise the MDL, so its ownership interest is not discoverable.

**Proposed Resolution:** The South Bend Clinic requests that you withdraw Request No. 20.

21. Any and all organizational charts maintained by the Healthcare Provider and/or any documents listing directors, officers, employees, and/or agents of the Healthcare Provider showing the names and positions of said directors, officers, employees, and/or agents and their relationship or rank within the Healthcare Provider.

**OBJECTION:** The Request is overbroad and not reasonably calculated to lead to the discovery of admissible evidence. The South Bend Clinic is not a Defendant in any of the lawsuits that comprise the MDL, so its organizational charts are not discoverable.

**Proposed Resolution:** The South Bend Clinic requests that you withdraw Request No. 21.

We look forward to discussing these objections with you when you return to the office.  
Thank you.

Sincerely,

BARNES & THORNBURG LLP

Joseph R. Fullenkamp

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